

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

PFIZER INC. and UCB PHARMA GMBH, )  
v. )  
ALKEM LABORATORIES, LTD., et al. )  
Plaintiffs, )  
Defendants. )  
C.A. No. 13-1110 (GMS)  
**CONSOLIDATED**

**PLAINTIFFS' ANSWERING CLAIM CONSTRUCTION BRIEF**

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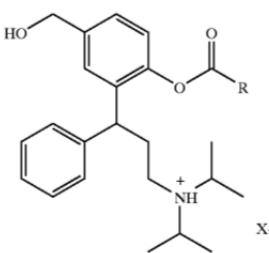
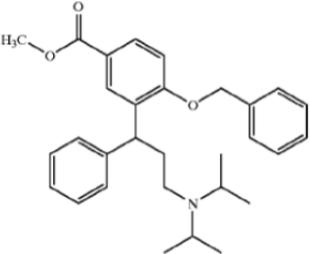
## **1. Introduction**

Defendants request construction of the entirety of claim 1 of U.S. Patent No. 6,858,650 (“the ’650 patent”) (J.A. 1), and the term “contact of the muscarinic receptor” in claim 4 of U.S. Patent No. 7,384,980 (“the ’980 patent”) (J.A. 2).

Claim 1 of the ’650 patent is a product claim, clear and unambiguous. *See* Defendants’ Opening Claim Construction Brief and Supporting Evidence (D.I. 107) (“Defs.’ Br.”) at 1. It must be construed to include any compound of general formula I, regardless of the method or process by which the compound is obtained.

The term “contact of the muscarinic receptor” in claim 4 of the ’980 patent is entitled to its plain meaning. No portion of the intrinsic evidence indicates that “contact” should be understood to mean “binding.” A person of ordinary skill in the art would not read the word so narrowly, and Defendants’ proposed construction is baseless.

## 2. Claim 1 of the '650 Patent

Term for Construction	Plaintiffs' Construction	Defendants' Construction
<p>Compounds of general formula I</p>  <p style="text-align: center;">Formula I</p> <p>in which R denotes C<sub>1</sub>-C<sub>6</sub>-alkyl, C<sub>3</sub>-C<sub>10</sub>-cycloalkyl, substituted or unsubstituted phenyl and X<sup>-</sup> is the acid residue of a physiologically compatible inorganic or organic acid.</p>	<p>Plain meaning.</p>	<p>The compounds of the claims of the '650 patent are limited to those obtained by the "crucial" reaction process of the specification wherein the intermediate compound of Formula III is (1)</p>  <p style="text-align: center;">Formula III</p> <p>subjected to hydrogenation followed by reduction, or vice versa, and (2) the resulting product is treated with an acylation agent.</p>

Claim 1 of the '650 patent is a product claim defined by a specific chemical structure.

Defendants propose to re-define claim 1 by adding a product-by-process limitation, thus limiting the claim to compounds made by a process that involves separately claimed intermediates. In doing so, Defendants attempt to read limitations from the specification into an unambiguous claim. Black-letter patent law provides that this is improper. *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012) citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (*en banc*). It bears noting that at least one Defendant apparently agrees with Plaintiffs. See Defs.' Br. at 1, n. 1 (Defendants Hetero USA Inc. and Hetero Labs Limited do not join in Defendants' proposed construction).

2.1      The Bar to Show Clear Disavowal is High and Not Met Here Where Defendants Seek to Re-Write the Entirety of the Claim

Defendants' proposed introduction of a limitation into claim 1 is premised on an alleged "clear disavowal of claim scope." Even a cursory reading of the decisions Defendants cite in support, however, reveals that only a single decision among them concerns the attempt made here: reading a *process* limitation into a *product* claim. *See* Defs.' Br. at 2-3, *citing Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1375 (Fed. Cir. 2007). *Andersen* is readily distinguishable, as that court read a process limitation in on the basis of a prosecution statement where the applicant unequivocally stated, "*the presently claimed composite is prepared by mixing the melted polymer and wood pulp, forming pelletized materials, cooled, then extruded.*" *Id.* at 1373, 1375 (emphasis added). Unlike this case, in *Andersen* the process in question was expressly linked during prosecution with the entire scope of the invention. Thus, the *Andersen* court read the process into the product claim.

All other cases cited by Defendants, albeit concerning the "clear disavowal" exception generally, relate to limitations of *product* claims to certain *product* limitations. *See, e.g., AstraZeneca AB, Aktiebolaget Hassle, KBI-E, Inc. v. Mutual Pharm. Co.*, 384 F.3d 1333, 1339 (Fed. Cir. 2004). *AstraZeneca*, while applying a very narrow exception to a term's plain meaning, nonetheless remains in harmony with statutory patent law principles recognizing distinct classes of patentable subject matter, and applies to product claims, not process claims. The cases cited by Defendants explain that the standard for clear disavowal is high, a standard Defendants fall short of here. *See GE Lighting Solutions, LLC v. AgiLight, Inc.* 750 F.3d 1304, 1309 (Fed. Cir. 2014) ("disavowal requires that the specification [or prosecution history] make[ ] clear that the invention *does not include* a particular feature") (emphases added); *AstraZeneca*, 384 F.3d at 1340 *citing Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir.

2002) (only “expressions of *manifest* exclusion or restriction” represent “a clear disavowal of claim scope”) (emphasis added).

The cases cited by Defendants, moreover, involve limiting or narrowing the scope of the claim, not re-writing it altogether. *See, e.g., AstraZeneca*, 384 F.3d at 1339; *X2Y Attenuators, LLC v. Int'l Trade Comm'n*, No. 2013–1340, 2014 WL 3029884 at \*3 (Fed. Cir. July 7, 2014) (limiting the “electrode [claim] terms” to a sandwich configuration). In so doing, Defendants ignore authority as to when it may be appropriate to convert a product claim into a product-by-process claim. *See, e.g., Biacore, AB v. Thermo Bioanalysis Corp.*, 79 F.Supp.2d 422, 456 (Robinson, J.) (D. Del. 1999) (“Typically, it is the wording of the claim which indicates that it is a product-by-process claim. For example, product-by-process claims employ terms such as ‘prepared in accordance with,’ ‘by the process of,’ whereby, ‘product of the process,’ ‘resulting from the process of,’ and ‘being produced by the process comprising.’”); *see also* Plaintiffs’ Opening Claim Construction Brief (“Pls.’ Br.”) at 8.

The alleged “clear disavowal” here does not rise to the level required by the law. The prosecution history, the specification, and the claims themselves make abundantly clear that the inventor described and claimed at least *four* distinct inventions: compounds (of Formula I and certain species thereof), methods of treating patients with those compounds, *methods of manufacturing* those compounds, and intermediates involved in those methods of manufacture. Indeed, Defendants themselves cite *Saunders Grp., Inc. v. Comfortrac, Inc.*, 492 F.3d 1326, 1331-33 (Fed. Cir. 2007), a decision supporting Plaintiffs’ position that Defendants’ construction would render later method of manufacture claims superfluous. The “crucial” and “special” buzz-phrases that litter Defendants’ moving brief pertain to and support the inventors’ distinctly

claimed *methods of manufacturing*. They are necessarily beside the point as to the construction of the product claims, such as claim 1.

## 2.2 Defendants Misstate the Prior Art

Defendants characterize the '650 patent as identifying disadvantages of compounds made by other processes and describe the “goal of the invention” as curing these alleged disadvantages. *See* Defs.’ Br. at 9, 16. Defendants allege that these compounds and the processes by which they are obtained are “prior art.” *See, e.g., id.* at 9, 13, 15-16, and 20. This is wrong. The compounds referenced by Defendants are the 3,3-diphenylpropylamines described in PCT/EP99/03212 (the “‘212 PCT”). *See id.* at 8-9 referencing '650 at col. 1, ll. 15-16. The '212 PCT is not prior art to the '650 patent because the '212 PCT published (1) after the priority date of the '650 patent, and (2) less than one year before the filing of the international application through which the '650 patent claims priority. 35 U.S.C. §§102, 363 (2012); MPEP § 706.02(f)(1). Defendants cite no basis to suggest otherwise.

The '212 PCT shares an inventor, Claus Meese, with the '650 patent, and issued as a series of patents, including four of the patents-in-suit here: U.S. Patent Nos. 7,384,980, 7,855,230, 7,985,772, and 8,338,478. As such, what the inventor describes as a benefit of the exemplary manufacturing process in the '650 specification is not at all a “criticism” of “prior art products [or processes],” but rather an observation from the continuous work underlying all of the patents-in-suit. Thus, the patentee’s statements as to the benefits of the exemplary process disclosed are not analogous to the “criticism” made by applicants in, for example, *AstraZeneca*, which was made in relation to “other products” *known* in the prior art. Defendants’ reach for the rare “clear disavowal” exception is fatal for this reason alone.

The '650 patent discloses a novel reaction process that offers advantages over what was previously known *to the inventor*. The '650 patent expressly and separately claims this process.

*See* '650 claims 7-16 and 18-20. Statements that characterize a reaction process as superior to what may have been previously known – to the inventor or otherwise – do not indicate an intention to limit *compound* claims to that reaction process. *See Epistar Corp. v. International Trade Com'n*, 566 F.3d 1321, 1336-37 (Fed. Cir. 2009). This is especially true where the novel process is itself separately claimed. *Evonik Degussa GmbH v. Materia Inc.*, No. 09-cv-636, 2013 WL 5780414, at \*10-12 (Hillman, J.) (D. Del. Sept. 30, 2013) (reviewing precedent that “it is a general rule in claim construction disputes that courts should not construe a term in one claim in a manner that would render its use in another claim redundant or superfluous”).

2.3     Selectively Quoting Terms Like “Crucial,” “Essential,” and “Special” Do Not Further a Showing of Disavowal

Defendants insist that the terms “special reaction process,” “crucial,” and “essential” in the '650 specification express clear disavowal. *See, e.g.*, Defs.' Br. at 9-10 and 12-14. When considered in context, these terms or phrases do not constitute clear disavowal. *Pfizer Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1373 (Fed. Cir. 2005) (“it is necessary to consider the specification as a whole, and to read all portions of the written description, if possible, in a manner that renders the patent internally consistent”) *citing Budde v. Harley-Davidson, Inc.*, 250 F.3d 1369, 1379 (Fed. Cir. 2001). None of the statements referenced by Defendants reaches the high bar for “clear disavowal.” *See* §2.1, *supra*. Selectively quoting these terms, while ignoring the remainder of the patent, is misguided and begs misinterpretation of the term. *Pfizer*, 429 F.3d at 1373. No statement involving these terms, either alone or in combination with other statements in the patent, constitutes clear disavowal.

The term “special reaction process” is used in the '650 patent twice, and only once in connection with “crucial.” The first time “special reaction process” is used, the '650 patent simply describes the surprising advantages of using the novel reaction process – i.e., the

distinctly claimed method of manufacture. *See* Defs.’ Br. at 9, *citing* ’650 at col. 1, l. 63 - col. 2, l. 3. The specification in no way indicates that the phrase is meant to limit each of the separate inventions claimed. In fact, given that the applicants sought, and were granted, separate claims to the “special reaction process” (*see* method claims 7-16 and 18-20), it is not only logical but required that the patent would describe the benefits of this method. *See* 35 U.S.C. §112 (2012).

The other time “special reaction process” appears, along with the sole use of “crucial” in the patent, is in reference to pathway intermediate steps and products. In full context, the specification provides:

In order to obtain the compounds in accordance with the invention in the form of their salts the *special reaction process* via particular intermediate stages and individually identifiable intermediates products is *crucial*.

*This is explained* using reaction diagram 1 (see FIG. 1), in which the conversions with R-configured compounds are described, ***but without this being restrictive.***

*See* ’650 at col. 9, ll. 21-27 (emphases added). Read in context, the full disclosure clearly instructs that the special reaction process is not “restrictive,” and therefore does not limit claim 1. *Pfizer*, 429 F.3d at 1373 (Fed. Cir. 2005).

The Federal Circuit has cautioned repeatedly that claim construction must be viewed through the specification as a whole. *See, e.g., Phillips*, 415 F.3d at 1315. Dependence on isolated terms, without reference to the specification as a whole, violates this canon of construction.

#### 2.4 Disclosure of a Single Embodiment Does Not Constitute or “Buttress” Disavowal

Defendants assert that “the fact that every one of the embodiments in the specification of the ’650 patent is made according to the special reaction process . . . further buttresses the conclusion that the patentees intended to limit the scope of the claimed invention.” Defs.’ Br. at 13; *see also id.* at 10. A claimed invention to a chemical compound cannot be confined to a single process simply because the patent describes one primary reaction process.

A patent can, and often does, have a single embodiment without being limiting. As the Federal Circuit declared in *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, “particular embodiments appearing in the written description will not be used to limit claim language that has broader effect. . . . [E]ven where a patent describes only a single embodiment, claims will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.” 381 F.3d 1111, 1117 (Fed. Cir. 2004); *see also Phillips*, 415 F.3d at 1323; *Liebel–Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906-07 (Fed. Cir. 2004); *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1380-81 (Fed. Cir. 2009). The fact that the ’650 patent exemplifies a “special reaction process” does not render claim 1 a product-by-process claim, nor does it disavow other processes by which the claimed compounds can be produced.

#### 2.5      The Certificate of Correction Does Not Support Defendants’ Position

Defendants imply that the Certificate of Correction, correcting “are that” to “are manufactured in that” at column 4, lines 45-46 of the ’650 patent, “underscores the criticality of the reaction process to obtaining the compounds of general formula.” Defs.’ Br. at 16-17. As a preliminary matter, this correction does not bear a connection to all of the inventions claimed in the patent, not least the compounds of claim 1.

More important, the text corrected was unquestionably befitting of a Certificate of Correction because the previously-existing sentence (with “are that”) was grammatically incorrect and required correction for clarity. Both the Patent Act and the Federal Circuit liberally recognize grammatical errors as appropriate grounds for a Certificate of Correction. *See* 35 U.S.C. §255; *Superior Fireplace Co. v. Majestic Prods. Co.*, 270 F. 3d 1358 (Fed. Cir. 2001). There is no indication that the correction was made to narrow claim scope, and Defendants’ citation should be ignored.

**3. Claim 4 of the '980 Patent is not Limited to “Binding of the Muscarinic Receptor”**

Term for Construction	Plaintiffs' Construction	Defendants' Construction
contact of the muscarinic receptor	Plain meaning.	binding to the muscarinic receptor

The term “contact” does not appear in the ‘980 specification, underscoring its common use and understanding. In Defendants’ view, “contact of the muscarinic receptor” should be construed to require more than just touching (i.e., “contacting” the receptor). *See* Defs.’ Br. at 18. They would require that 5-HMT must “have a biological impact” at the receptor and would have the Court limit “contact” to the specific type of “binding” described in the patent. *Id.* at 18-19 (discussing the Receptor Binding Study at col. 54, l. 53 - col. 55, l. 53 of the ’980 patent and the January 18, 2008 Amendment at 2 and 8). This is incorrect. In claim 4, “contact” refers to the action of 5-HMT “contacting” the receptor to antagonize it. *See* Pls.’ Br. at 13-14. The term “binding,” referenced in columns 54-55 of the ‘980 patent, is a specific form of “contact” that also implies a particular pharmacological effect associated with the affinity of 5-HMT to the receptor.

There is no basis to limit the claim here. The Federal Circuit “has cautioned against limiting the claimed invention to preferred embodiments or specific examples in the specification.” *Tex. Instruments, Inc. v. U.S. Int'l Trade Comm'n*, 805 F.2d 1558, 1563 (Fed. Cir. 1986). Where a patent describes only a single embodiment, claims should not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope. *See, supra*, §2.4. While binding certainly would be understood to “cause [a] therapeutic effect resulting from antagonizing the receptor,” as Defendants explain, there is no indication in the patent that the specific binding study of the patent is the only means to achieve or demonstrate this result.

Nor should citing to the Receptor Binding Study during prosecution as support for the claim language limit the scope of the claim to that language. *See Grober v. Mako Prods., Inc.*, 686 F.3d 1335, 1341-42 (Fed. Cir. 2012) (“[W]hile the prosecution history can inform whether the inventor limited the claim scope in the course of prosecution, it often produces ambiguities created by ongoing negotiations between the inventor and the PTO. . . . Therefore, the doctrine of prosecution disclaimer only applies to unambiguous disavowals.”). Merely identifying support does not indicate an intention to narrow.

According to Defendants, moreover, another term within the same claim – antagonizing – already connotes “binding.” *See* Defs.’ Br. at 19 (“binding is necessary to antagonize”). As such, adopting Defendants’ proposed construction would render the term “antagonizing” in the same claim meaningless and/or superfluous, and accordingly should be rejected under well-settled law of claim construction. *See Merck & Co. v. Teva Pharmas. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005) (“A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so.”); *see also Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006) (“claims are interpreted with an eye toward giving effect to all terms in the claim”).

Defendants’ narrowing construction should be denied, and “contact” should be given its plain English meaning.

#### **4. Conclusion**

For the above reasons, and those stated in Plaintiffs’ Opening Claim Construction Brief, Plaintiffs request that the Court construe the terms in the manner proposed by Plaintiffs. Defendants have proffered numerous arguments that are controverted by case law and reason.

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September 12, 2014

**CERTIFICATE OF SERVICE**

I hereby certify that on September 12, 2014, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

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